



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,823	11/07/2005	Robert K. Yang	1199-13 PCT/US	2398

7590
Daniel A Scola
Hoffmann & Baron
6900 Jericho Turnpike
Syosset, NY 11791

10/30/2009

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

10/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,823	Applicant(s) YANG ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-15, 18 and 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16, 17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/29/05; 8/12/09</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement filed 07/15/09 and the Information Disclosure Statements (IDS) filed 04/29/05 and 08/12/09 is acknowledged.

Applicant's election with traverse of Group I (claims 1-20) and Election of Species (b) – *with* active ingredient (reading on claims 1-10, 16, 17, 19 & 20) in the reply filed on 15 July 2009 is acknowledged. The traversal is on the ground(s) that the restriction is improper and that a search of claims 1-28 would not impose a serious burden. This was not found to be persuasive because as stated in the Restriction requirement (filed 06/23/09), the different groups each entail distinct features and elements that are unique to each group presented. For example, the Group I product requires the inclusion of voids to enable increased surface area, whereas the Group II and III inventions do not require the use of such voids. Moreover, the groups are distinct in that Group I is drawn to a dosage vehicle (product), whereas Group II is drawn to a package and Group III is drawn to a method of storing and dispensing. Each of the different groups would have unique issues with respect to patentability, enablement and written description. In addition, the different groups would each entail a separate search in both patent- and non-patent databases, based on their distinct classification, and there is no expectation that the searches would be coextensive in scope. This creates an undue search burden upon the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-15, 18 and 21-28 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

Art Unit: 1615

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 15 July 2009.

Claims 1-28 are pending in this action. Claims 11-15, 18 and 21-28 have been withdrawn (based on nonelected invention). Claims 1-10, 16, 17 and 19-20 have been examined in this action. Claims 1-10, 16, 17 and 19-20 are rejected.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/29/05 and 8/12/09 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 16, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (USPN 7,425,292).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the

Art Unit: 1615

reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Yang et al. teach rapidly dissolving films containing active ingredient distributed throughout the film (see col.1, lines 10-17). The films can be divided into equally sized dosage units having substantially equal amounts of each compositional component present (col. 3, lines 49-60). A pharmaceutical or cosmetic active can be incorporated into the film (col.6, lines 8-15). Materials employed in the film are discussed at column 9, lines 8-64. The films are self-supporting (col. 16, lines 3-8). The films are cut into individual doses to ensure active agent uniformity (col. 20, lines 62-65).

Yang meets the edible film as claimed based upon the same features and elements. Thus, Yang renders the instant invention prima facie obvious to one of ordinary skill in the art.

Claims 1-7, 16, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cremer et al. (USPN 6,655,112).

Cremer et al. teaches a primary packaging unit for film-like or wafer-like administration forms for oral application in that a plurality of dosage units are individually sealed and are present in a primary packaging unit and there are perforations between the compartments which enable the separation of the individual compartments (see Abstract); (col. 1, lines 44-55); (col. 3, line 55 – col. 4, line 47). The unit includes therapy patterns by means of printing. Thus, for example, the packaging unit can be a 7-day package with seven dosage units of a drug to be taken once a day (col. 4, lines 55-65).

Art Unit: 1615

Cremer meets the edible film as claimed based upon the same features and elements. Thus, Cremer renders the instant invention prima facie obvious to one of ordinary skill in the art.

Claims 1-10, 16, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 00/42992).

Chen et al. teaches a dosage unit comprising a water-soluble hydrocolloid and a mucosal surface-coat forming film, including an effective dose of active agent (see Abstract). The devices of Chen include a heat sealed single pouch, a multi-unit blister card, multi-unit dispensing pack and a perforated film strip and a single dose film (p. 6, lines 4-8). Although Chen does not teach the inclusion of voids, they do teach that the surface area can be adjusted based on various factors (p. 6, line 30 - p. 7, line 10). Also see page 16 of Chen.

Chen meets the edible film as claimed based upon the same features and elements. Thus, Chen renders the instant invention prima facie obvious to one of ordinary skill in the art.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

October 26, 2009